

COMPANY ANNOUNCEMENT

Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

July 03, 2019

FDA Publish Date:

July 05, 2019

Product Type:

Drugs

Over-the-Counter Drugs

Reason for Announcement:

Potential for nonsterility

Company Name:

Altaire Pharmaceuticals, Inc.

Brand Name:

Equate and Support Harmony

Product Description:

Over-the-Counter (OTC) drug products

Company Announcement

Altaire Pharmaceuticals, Inc., announces today that it is voluntarily recalling the Over-the-Counter (OTC) drug products and lots, within expiry, sold at Wal-Mart during the time period as indicated in the tables below. As a precautionary measure, Altaire is initiating the recall due

to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. This recall is being carried out to the retail level and is only for the specific lots listed above. No other lots are being recalled.

Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death. To date, Altaire has received no reports of adverse events, nor has Altaire obtained any out of specifications results including Sterility testing, for the products.

Product Description: Equate Restore Tears Lubricant Eye Drops Twin Pack W-M item #: 552374320 NDC #: 49035-189-49 Package Size: 2 x 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 17196 | 07/19 | 08/15/2017 |
| 17292 | 09/19 | 11/03/2017 |
| 17355 | 11/19 | 12/22/2017 |
| 19040 | 02/21 | 03/26/2019 |

Product Description: Equate Eye Allergy Relief Drops W-M item #: 567371432 NDC #: 49035-887-13 Package Size: 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 19128 | 05/21 | 06/20/2019 |
| 19009 | 01/21 | 01/28/2019 |
| 19003 | 01/21 | 02/21/2019 |
| 19034 | 01/21 | 03/07/2019 |
| 19060 | 02/21 | 04/22/2019 |
| 19061 | 02/21 | 05/21/2019 |
| 18252 | 10/20 | 11/21/2018 |
| 18058 | 03/20 | 03/22/2018 |
| 18224 | 09/20 | 09/26/2018 |
| 18185 | 07/20 | 08/27/2018 |
| 18152 | 06/20 | 07/05/2018 |
| 18159 | 06/20 | 07/18/2018 |
| 18091 | 04/20 | 06/07/2018 |
| 18090 | 04/20 | 04/27/2018 |

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 18069 | 03/20 | 04/04/2018 |

Product Description: Equate Sterile Lubricant Styel Ointment W-M item #: 563031651 NDC #: 49035-875-50 Package Size: 3.5 gram

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| SAJ | 01/21 | 03/23/2018 |
| SFE | 06/21 | 07/05/2018 |
| SIA | 09/21 | 10/23/2018 |
| RIE | 09/20 | 09/28/2017 |
| REH | 05/20 | 07/21/2017 |
| RAD | 01/20 | 05/23/2017 |
| TAH | 01/22 | 02/14/2019 |
| TDD | 04/22 | 05/29/2019 |

Product Description: Equate Comfort Gel Lubricant Eye Gel Twin Pack W-M item #: 552374319 NDC #: 49035-197-49 Package Size: 2 x 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 17384 | 12/19 | 01/17/2018 |
| 17259 | 08/19 | 10/27/2017 |
| 19002 | 01/21 | 01/22/2019 |
| 19041 | 02/21 | 04/09/2019 |
| 18222 | 09/20 | 09/25/2018 |
| 18084 | 04/20 | 06/15/2018 |

Product Description: Equate Restore PM Nighttime Lubricant Eye Ointment W-M item #: 551282425 NDC #: 49035-191-50 Package Size: 3.5 gram

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| SKG | 08/21 | 12/18/2018 |
| SHK | 08/21 | 10/09/2018 |

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|-------------------|------------------------|---------------------------------------|
| SHJ | 08/21 | 09/13/2018 |
| SEC | 05/21 | 07/13/2018 |
| SCB | 03/21 | 01/14/2019 |
| SBC | 02/21 | 03/21/2019 |
| RLB | 12/20 | 12/27/2017 |
| RBB | 02/20 | 04/28/2017 |
| RHR | 08/20 | 10/04/2017 |
| RFK | 06/20 | 07/28/2017 |
| RAB | 01/20 | 03/21/2017 |
| TAD | 01/22 | 01/25/2019 |
| TAQ | 01/22 | 03/18/2019 |
| TBI | 02/22 | 04/29/2019 |
| TDB | 04/22 | 06/07/2019 |
| QHE | 08/19 | 09/27/2016 |
| QJD | 10/19 | 12/07/2016 |
| SGE | 07/21 | 08/07/2018 |

Product Description: Equate Night & Day Restore Tears Lubricant Eye Pack W-M item #: 567368000 NDC #: 49035-883-59 Package Size: 3.5g and 15mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|-------------------|------------------------|---------------------------------------|
| KT19146 | 02/21 | 06/05/2019 |
| KT18133 | 04/20 | 12/12/2018 |
| KT18194 | 07/20 | 01/15/2019 |
| KT18129 | 02/20 | 05/25/18 |

Product Description: Equate Support Advanced Twin Pack W-M item #: 567371433 NDC #: 49035-885-49 Package Size: 2 x 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|-------------------|------------------------|---------------------------------------|
| 19137 | 05/22 | 06/06/2019 |
| 19022 | 01/22 | 02/18/2019 |

Product Description: Equate Support Advanced Lubricating Eye Drops Dose Preservative Free
W-M item #: 563031654 NDC # 49035-882-54: Package Size: 25 count (0.6 mL fill):

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| RKP | 11/19 | 01/08/2018 |
| RIN | 09/19 | 12/22/2017 |
| SLC | 12/20 | 01/16/2019 |
| RIF | 09/19 | 10/10/2017 |
| TBE | 02/21 | 03/26/2019 |
| TBI | 02/21 | 05/15/2019 |
| SHB | 08/20 | 10/03/2018 |

Product Description: Equate Support Advanced Lubricant Gel Drops Multi Dose Preservative Free
W-M item #: 567367998 NDC #: 49035-882-52 Package Size: 7.5 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 19015 | 01/21 | 02/06/2019 |
| 19117 | 04/21 | 05/20/2019 |
| 18080 | 07/20 | 08/02/2018 |
| 18111 | 05/20 | 05/25/2018 |

Product Description: Equate Support Moisture Lubricant Eye Drops W-M item #: 553503238
NDC #: 49035-145-10 Package Size:10 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 19011 | 01/21 | 04/01/2019 |
| 18052 | 02/20 | 03/26/2018 |
| 18266 | 10/20 | 01/15/2019 |
| 18178 | 07/20 | 08/20/2018 |
| 17385 | 12/19 | 01/24/2018 |

Product Description: Support Harmony Lubricant Eye Drops W-M item #: 553503238 NDC #: 49035-145-10 Package Size: 10 mL (Note: Support Harmony packaging was discontinued in January 2018.)

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 17290 | 09/19 | 11/03/2017 |

The products are manufactured and labeled exclusively for Wal-Mart. Altaire ships the products labeled for Wal-Mart only to Wal-Mart. The products are distributed at the retail level by Wal-Mart. Altaire has also requested that Wal-Mart notify its customers.

Altaire has notified Wal-Mart by e-mail on July 3, 2019 announcing the recalls of the products/lots identified herein, with specific directions for return of all units of the impacted lots.

Customers with questions regarding this recall can contact Altaire Pharmaceuticals Inc., by calling 1-800-258-2471, or e-mailing otcdruggist@aol.com (mailto:otcdruggist@aol.com) Monday thru Friday from 8:30 a.m. to 5:00 p.m. ET. Customers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm (<http://www.fda.gov/medwatch/report.htm>)
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm (<http://www.fda.gov/MedWatch/getforms.htm>) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Altaire takes its mission of customer safety and providing quality products very seriously. The company is committed to, and diligently working to, ensure the sufficiency of Quality Assurance controls over critical systems in its manufacturing facility.

Company Contact Information

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